



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/US91/08207</p> <p>(22) International Filing Date: 29 October 1991 (29.10.91)</p> <p>(30) Priority data: 605,494 30 October 1990 (30.10.90) US</p> <p>(71) Applicant: THE WEST COMPANY, INCORPORATED [US/US]; West Bridge Street, Phoenixville, PA 19460 (US).</p> <p>(72) Inventor: PAPCIAK, Charles ; 511 Pine Creek Road, Ex- ton, PA 19341 (US).</p> <p>(74) Agents: RENZ, Eugene, E., Jr. et al.; 205 North Monroe Street, P.O. Box 2056, Media, PA 19063 (US).</p>		<p>(81) Designated States: AT, AT (European patent), AU, BE (European patent), BR, CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent), SU<sup>+</sup>.</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: DECORATION, IDENTIFICATION AND DIFFERENTIATION CLOSURE SYSTEM</p> <div data-bbox="738 1270 1096 1680"> </div> <p>(57) Abstract</p> <p>A system for pharmaceutical product identification, comprising a closure (10) on a pharmaceutical container, including a cap seal (11) having a dependent skirt and an upwardly facing top (13). The closure and overcap (17) have identifying indicia in the form of color and words to cooperatively convey information to the user of said container.</p>		

# + DESIGNATIONS OF "SU"

Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

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DECORATION, IDENTIFICATION AND  
DIFFERENTIATION CLOSURE SYSTEM  
BACKGROUND ART

Pharmaceutical products are sold with extensive labeling. Packaging and containers are filled with instructions, warnings, and other information. Goods which can be packaged in vials, such as unit doses of medicaments, are packaged with written instructions inside the box or other package which contains the vial. These vials are intended for use with syringes and are to be applied to the patient at the bedside or other places of treatment.

Typically, nurses will be assigned to give medicines and the like to a number of patients at one period of time. Often times, the nurse administering the medicine will have an entire tray or even a cart full of medicines to be given to a part or all of a floor in a hospital. In order to understand the background of the present invention and the environment in which it is intended to be used, it is necessary to visualize a health care worker assembling medicine on a cart or tray for a visit to several patients. Typically, the nurse or health care worker will have individual instructions for each patient, and will place those instructions on separate locations on the tray or cart. Reading each set of instructions separately, the health care worker will then place the appropriate medicines from the pharmacy department of the hospital on the respective instruction sheets or slips of paper.

When tablets or pills are given, they are often placed in disposable cups and one can be relatively certain that the correct patient will be given the correct medicine. Similarly, when medicines are to be given with a syringe, unit dose vials of the correct medicine in the correct amount can be placed on the patient's instruction list or chart and there is every expectation that the appropriate medicine will be delivered to the appropriate patient.

In some instances, however, the medicine which is to be given to the patient will be mixed at the point of administration or use. For example, dilution  
5 instructions are often times provided for medicine which, if it is not diluted, can cause serious problems. This information is given with the instructions from the doctor or pharmacist in most cases. In addition, this information is often printed on the vial label or  
10 container itself. Every effort is made to insure that the instructions are followed at the point of administration.

A problem arises when the health care worker relies upon  
15 information which is placed on the cap of the container, particularly in containers which have a removable protective cap. These caps are essential to maintain sterile conditions for the medicines, and are designed to be easily removed by a flipping motion of the thumb,  
20 while the vial is held in one hand. At that point, the nurse can then add the diluent or perform whatever additional steps are necessary as the medicine is transferred to a syringe and then to the patient. Occasionally, however, the health care worker will remove  
25 more than one cap, particularly if a number of treatments are all to be given at one time. Also, even when one medicine is being administered, if it is to be diluted and if the diluent is supplied separately, caps from many containers must be removed. If the container  
30 without the cap does not contain the appropriate instructions, or if there is some way for the container to be separated from the cap, thereby losing the instructions, an unnecessary risk is taken.

35 While every intention is to avoid confusion and haste, sometimes it is unavoidable that the health care worker will have too many patients to treat in too short of

time, and the very real possibility exists that the medicine given to a particular patient may not be precisely the treatment which the doctor has prescribed. While sometimes too much or too little diluent may not  
5 cause a significant problem, the very real possibility exists that improper administration of medicine can cause serious harm to the patients being treated.

As simple as it sounds, there have been many tragic  
10 examples of mistakes being made by health care personnel. These mistakes have cost lives and have endangered the lives of many others. For example, many deaths occur nationally each year because of a mix-up of sodium chloride and potassium chloride the latter of which, if  
15 not diluted, can cause death. And yet, at the present time, there is no system for product identification of pharmaceutical products and the like which is designed specifically for point of application treatments. In many instances, where removable outer caps are used for  
20 protection of the patient and maintenance of sterile conditions, after removal the cap is placed near the vial to keep the instructions on the cap near the vial. Yet there is no real assurance that the cap and vial are properly matched at a later time when the busy health  
25 care worker picks up the medicine for a particular patient. If he or she glances at the wrong cap, a mistake of potentially fatal consequences can take place.

Accordingly, it is an object of this invention to provide  
30 additional safety at the point of use of medicines. It is a specific object of this invention to provide a system for pharmaceutical product identification which can be used at the point of application to insure the proper identification and other information be  
35 communicated to the nurse or other health care personnel. Other objects will appear hereinafter.

DISCLOSURE OF THE INVENTION

It has now been discovered that the above and other objects of the present invention may be accomplished in the following manner. Specifically, a new system for pharmaceutical product identification has been developed. The system includes a closure on a pharmaceutical container, including an aluminum cap seal which has a first identifying indicia. Also provided is a removable overcap protecting the closure and having a second identifying indicia. The first and second indicia cooperatively convey information to the user of the container. Information is conveyed both before and after the overcap is removed.

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Examples of information which is conveyed by the first and second indicia are safety messages, identity messages, dosage messages, restriction on use warnings, color codings and other instructions. In addition, the indicia may convey contents, brand names, dosage strengths and other information.

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BRIEF DESCRIPTION OF THE DRAWINGS

These and other objects of the present invention and the various features and details of the operation and construction thereof are hereinafter more fully set forth with reference to the accompanying drawings, where:

Fig. 1 is an enlarged elevational view of one embodiment shown in section illustrating the attachment of a removable overcap onto a closure seal.

Figs. 2 - 5 are perspective, exploded views of different embodiments of the present invention.

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BEST MODE FOR CARRYING OUT THE INVENTION

As shown in Fig. 1, the system of the present invention includes a device, shown generally by the reference numeral 10, which includes, among other parts of the closure system, a cap seal 11 which is normally made from aluminum. The cap seal includes a top 13, on which a first identifying indicia may be placed. The top terminates inwardly at the center hole 15 which is designed to accept the overcap 17. Overcap 17, shown in Fig. 1, is typically a plastic button like member which has been formed or molded from plastic and which contains a second identifying indicia. The annular dependent ring 19 is sized to fit hole 15 and, during assembly, is formed outward, shown at 19a as the dot and dash view of cap 17a fits on top 13. This entire assembly is then placed on a rubber stopper or other closure. When the cap 17a is desired to be removed, the health care worker merely presses upward against the cap 17a, fracturing frangible portions and exposing the top 13.

Shown in Fig. 2 is a pharmaceutical product identification system in which the cap 21 is plain and the top 23 has been colored. Overcap 27 is clear, thereby allowing the information contained on the top to be seen both before and after removal of cap 27. This ensures that the health care worker using this system will have whatever information is desired by the pharmacist, drug manufacturer, or physician, as need be, before and after the cap is removed.

Similarly, in Fig. 3, the plain cap 31 has printed information such as advertising or instruction such as "must be diluted" for potassium chloride. This information is placed on top 33 which is visible through clear cap 37, both before and after the cap 37 has been removed. In this case, whether color coding or

information is important for the user, that information can be relayed without any possibility of the information being thrown away with the cap.

- 5 In Fig. 4, a plain cap 41 with a plain top 43 include a printed cap 47 which is primarily for advertising purposes in this example.

10 In Fig. 5, a colored cap 51 and colored shoulder 53 are matched with a similarly colored cap 57. In this case, the information is contained on cap 57, but the similarity of color coding allows the health worker to match the cap to the appropriate vial or container, even after the cap 57 has been removed. Of course, the vials, 15 not shown, to which the seal and cap are added may be clear or the same or different colors from the seal and/or cap.

In each case, the information conveyed by the first 20 identifying indicia on the cap seal is cooperatively combined with the information conveyed by the indicia on the removable overcap, to provide a fail-safe redundancy of information at the point of use of the container to which they are applied.

25 As has been noted, safety messages such as the appropriate material for dilution or the quantity of dilution can be conveyed with both the first and second indicia, either duplicating the information or combining 30 to convey that information. Extra assurances are given when the same message is on both the cap and the top of the container seal. Similarly, restrictions on use or other warnings can be used. For example, the cap may state that dilution is required while the seal top may 35 state that the contents cannot be used without dilution.

One particular example of the present invention which illustrates the important contribution made toward safety is the use of identical indicia, such as black coloring or warnings that the contents must be diluted before use, on both the closure and the overcap. Thus, if the overcap is removed by a nurse prior to the time when the contents are to be diluted, there is less likelihood that the instructions will be ignored because the same instructions are contained on the closure itself. If the overcap is misplaced or becomes mixed up with other overcaps, the safety alert is still present on the closure. Prior to removal of the overcap, when the nurse is selecting medicines to take to the patient, she can rely on the overcap before it has been removed to convey the same necessary information. As she takes the steps to properly prepare the medicine cart or the like, removal of the cap will not cause the necessary information to be separated from the pharmaceutical container.

In the preferred embodiment, cap 17 may be manufactured from plastic such as polypropylene or other similar plastics. The specific material is not critical, as long as other functional requirements are met. The plastic should be suitable for receiving printing or other information after formation, and such be susceptible to being colored prior to manufacture. Similarly, the seal can be made from a number of materials, although aluminum is the preferred material since it is suitable for application of colors through dies and lacquers, and since it is receptive to printing.

It is particularly important that the product be immediately and visually identified. Messages, instructions or warnings must be highly visible and for that reason the printing process must be sufficient to clearly define the color and/or information which is

intended to be placed on either the cap, under seal, or both. The colors should be easily duplicated, particularly since the cap and seal are often made at different points in the manufacturing process. The products should be autoclavable, and thus would stand temperatures in excess of 121°C for sufficient time to sterilize the products. It should be noted that the information added to the products by the present invention is on the exterior and is never in contact with the contents of the vial. Accordingly, there is no reason for expensive qualification testing and the like.

In a preferred embodiment, the system of this invention contemplates the use of a color indicia and instructive words on both the pharmaceutical container closure and the removable overcap. The color indicia of the closure and the overcap cooperatively convey information to the user of the container. The instructive words also cooperatively convey information to the user.

For example, a black closure and a black overcap together tell the user that the two were originally together and should be kept together, as well as telling the user that the contents must be diluted. The instructive words also tell the user that the contents must be diluted prior to administration to the patient. Separation of the overcap from the closure also conveys information to the user.

While particular embodiments of the present invention have been illustrated and described herein, it is not intended to limit the invention. Changes and modifications may be made therein within the scope of the following claims.

CLAIMS

What is claimed is:

- 5 1. A system for pharmaceutical product identification, comprising;  
a closure on a pharmaceutical container, including  
a cap seal having a dependent skirt and an upwardly  
facing top with a color indicia and an instructive  
10 indicia; and  
a removable overcap having a color indicia and an  
instructive word indicia;  
said color indicia of said closure and overcap  
cooperatively conveying information to the user of said  
15 container and said instructive word indicia also  
conveying information to the user of said container,  
whereby separation of said overcap from said cap seal  
also conveys information to said user.
- 20 2. The system of Claim 1, wherein said color indicia  
convey safety messages.
3. The system of Claim 1, wherein said instructive  
word indicia convey safety messages.
- 25 4. A system for pharmaceutical product identification,  
comprising:  
a closure for a pharmaceutical container, including  
a cap having a top and a dependent skirt, said cap having  
30 a first identifying indicia; and  
a removable overcap covering said first indicia  
connected to said cap by a frangible attachment, said  
overcap having a second identifying indicia thereon;  
said first and second indicia cooperatively  
35 conveying information to a user.

5. The system of Claim 4, wherein said first and second indicia convey safety messages.

6. The system of claim 4, wherein said first and second indicia convey the same message.

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7. The system of Claim 4, wherein the first and second indicia convey dosage information.

8. The system of Claim 4, wherein said first and second indicia convey restriction on use information.

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9. The system of Claim 4, wherein said indicia convey information using color coding.

10. The system of Claim 4, wherein said removable overcap is clear.

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11. The system of Claim 4, wherein said first and second indicia convey source of goods information.

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12. A system for pharmaceutical product identification, comprising:

a container having a pharmaceutical product therein;

25 a closure on said pharmaceutical container, including a cap having a top and a dependent skirt, said cap having a first identifying indicia; and

a removable overcap connected to said cap by a frangible attachment, said overcap having a second identifying indicia thereon, said first and second indicia cooperatively conveying information to a user.

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13. The system of Claim 12, wherein said first and second indicia convey safety messages.

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14. The system of Claim 12, wherein said first and second indicia convey the same message.

15. The system of Claim 12, wherein the first and second indicia convey dosage information.

16. The system of Claim 12, wherein said first and second indicia convey restriction on use information.

17. The system of Claim 12, wherein said indicia convey information using color coding.

18. The system of Claim 12, wherein said removable overcap is clear.

19. The system of Claim 12, wherein said first and second indicia convey source of goods information.

20. A system for pharmaceutical product identification, comprising:

a container having a pharmaceutical product therein;

a closure on said pharmaceutical container, including a cap having a top and a dependent skirt, said cap having a first identifying indicia; and

a removable overcap connected to said cap by a detachable attachment, said overcap having a second identifying indicia thereon, said first and second indicia cooperatively conveying information to a user.

21. A system for pharmaceutical product identification, comprising:

a closure on a pharmaceutical container, including a cap seal having a dependent skirt and an upwardly facing top with a first color indicia and a first instructive indicia in the form of words; and

a removable overcap having a second color indicia and a second instructive indicia in the form of words;

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said first and second color indicia cooperatively conveying information to the user of said container and said first and second instructive indicia conveying information to the user of said container, whereby  
5 separation of said overcap from said cap seal also conveys information to said user.

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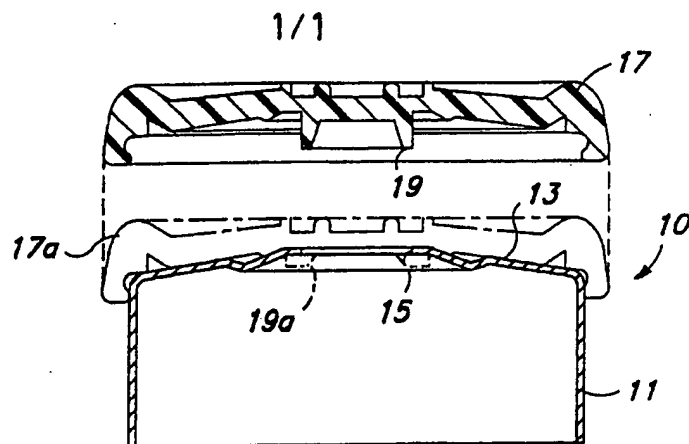
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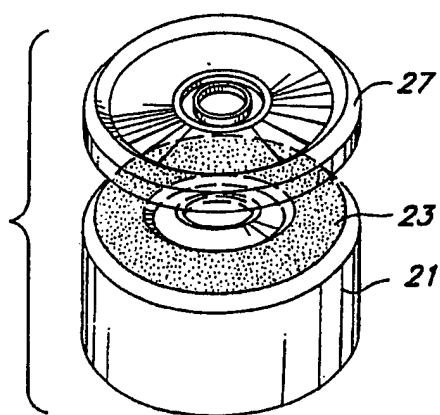
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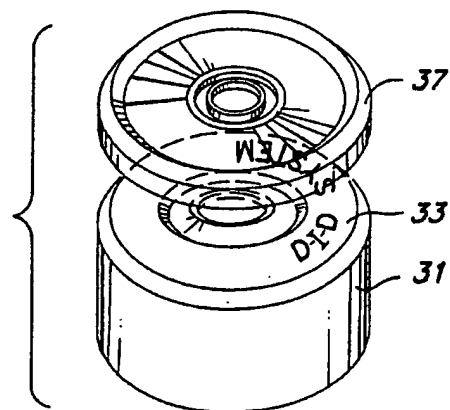
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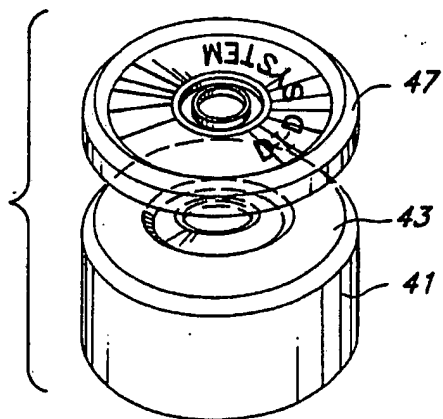
**FIG. 1**



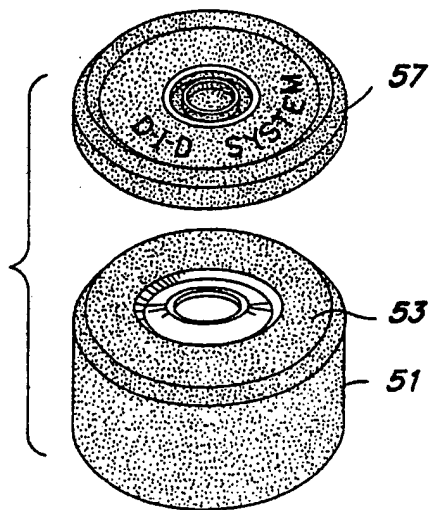
**FIG. 2**



**FIG. 3**



**FIG. 4**



**FIG. 5**

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/08207

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (If several classification symbols apply, indicate all) <sup>1</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(5): B65D 41/62		
U.S. CL. 206/459, 534; 215/230; 220/254		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>2</sup>		
Classification System	Classification Symbols	
U. S. CL.	40/306,307,310,311,313; 206/459,528,534,538,539; 215/230; 220/254,256,258	
Documentation Searched other than Minimum Documentation to the extent that such documents are included in the fields searched <sup>3</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>4</sup></b>		
Category <sup>5</sup>	Citation of Document, <sup>6</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>3</sup>
X	US, A, 4,749,093 TRICK 07 JUNE 1988	1,3
Y	See entire reference.	2, 13-19
X	US, A, 4,687,113 REEVE 18 AUGUST 1987	4-9,11-17,19,20
Y	See entire reference.	10,18,21
X	US, A, 4,365,722 KRAMER 28 DECEMBER 1982	1,3
Y	See entire reference.	2,21
Y	US, A, 4,723,673 TARTAGLIA ET. AL. 09 FEBRUARY 1988	10,18
	See entire reference.	
A	US, A, 3,225,914 KLEIN ET. AL. 28 DECEMBER 1965.	ALL
	See Figure 2.	
A	US, A, 4,346,833 BERNHARDT 31 AUGUST 1982	ALL
	See Figure 2.	
A	US, A, 4,347,804 VILLA-REAL 07 SEPTEMBER 1982	ALL
	See entire reference.	
A	US, A, 4,548,157 HEVOYAN 22 OCTOBER 1985	ALL
	See Figure 1.	
A	US, A, 4,616,750 NOUWEN 14 OCTOBER 1986.	ALL
	See Figure 1.	
<p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"A" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
01 FEBRUARY 1992	21 FEB 1992	
International Searching Authority	Signature of Authorized Officer	
ISA/US	JIMMY G. FOSTER	

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 4,779,733 KILIAN 25 OCTOBER 1988. See Figure 2.	ALL
A	US, A, 4,964,512 INGRAM ET. AL. 23 OCTOBER 1990. See Figure 1.	ALL
A	US, A, 4,572,376 WRENNALL 25 FEBRUARY 1986 See entire reference.	ALL

V ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

- 1 ☐ Claim numbers \_\_\_\_\_ because they relate to subject matter not required to be searched by this Authority, namely:
  
- 2 ☐ Claim numbers \_\_\_\_\_ because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
- 3 ☐ Claim numbers \_\_\_\_\_ because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This International Searching Authority found multiple inventions in this international application as follows:

- 1 ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
- 2 ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
- 3 ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
- 4 ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest:

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.